IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 4 CASES LISTED IN PLAINTIFFS' EXHIBIT A.	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE THE TESTIMONY OF DEFENDANTS' EXPERT, HARVEY A. WINKLER, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this memorandum in opposition to Plaintiffs' motion to exclude the testimony of Defendants' Expert, Harvey A. Winkler, M.D. (Pls. Motion [ECF No. 3671]; Pls. Mem. [ECF No. 3675]).

INTRODUCTION

Dr. Winkler is a practicing urogynecologist with board certifications in Obstetrics and Gynecology and in Female Pelvic Medicine and Reconstructive Surgery. Dr. Winkler has issued two general expert reports in the Ethicon Wave 4 cases regarding Gynemesh PS and Prolift ("Prolift Report") (Ex. A) and TVT and TVT Exact ("TVT Report") (Ex. B) outlining his anticipated testimony that will assist the jury in understanding a number of issues. Plaintiffs argue the Court should exclude certain opinions of Dr. Winkler under *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), including testimony regarding: (1) the completeness of Ethicon's warnings and the knowledge common to pelvic floor surgeons; (2) the materials used in TVT; (3) the safety and effectiveness of mechanically cut mesh and laser cut mesh; (4) the

comparative safety of pelvic mesh products and alternative treatments; and (5) Plaintiffs' claims regarding mesh degradation.

None of Plaintiffs' arguments present a true *Daubert* challenge. Rather, they are a thinly veiled effort to exclude relevant evidence supporting Defendants' positions in this litigation. Dr. Winkler is qualified to render the opinions offered in his reports and at his depositions, and has supported those opinions with facts from the record, his review of the relevant medical literature and his experience in his own clinical and teaching practices. Accordingly, Dr. Winkler's opinions are based on sound methodology. For these reasons, Plaintiffs motion should be denied in its entirety.

DR. WINKLER'S PROFESSIONAL BACKGROUND

Dr. Winkler is board certified in Obstetrics and Gynecology and Female Pelvic Medical and Reconstructive Surgery. He is a member of the American Urogynecologic Society (AUGS), International Urogynecological Association (IUGA), American Association of Gynecological Laparoscopists (AAGL), and the American Institute of Minimally Invasion Surgery (AIMIS). After graduating from the Albert Einstein College of Medicine in 1992, and completing his residency in Obstetrics and Gynecology at Montefiore Medical Center in 1996, in 1998 he completed a fellowship in Urogynecology at Evanston Hospital, which was then affiliated with Northwestern University, under the tutelage of Dr. Peter Sand, an early pioneer of Urogynecology. In July of that year, he returned to Maimonides Medical Center to launch the Urogynecology Division there and was appointed the Chief of the Division which he developed into a local center of excellence.

Dr. Winkler amplified his teaching expertise in May 2002, when he moved to North Shore LIJ (now known as Northwell) and, in 2006, was appointed Co-Chief of the Division of Urogynecology: Female Pelvic Medicine and Reconstructive Surgery. He pioneered and assembled the fellowship program in Female Pelvic Medicine and Reconstructive Surgery for Hofstra Northwell School of Medicine for which he was appointed Program Director. He is responsible for the resident education curriculum and rotations in Urogynecology at North Shore University Hospital and Long Island Jewish Medical Center.

Dr. Winkler has extensively researched and contributed to the medical literature on the surgical treatment of pelvic floor disorders. He is the Assistant Investigator in Patient Oriented Research at the Feinstein Institute for Medical Research of Northwell Health where he has been involved in research projects and studies on pelvic organ prolapse and urinary incontinence. He has presented numerous abstracts, published peer-reviewed articles on pubovaginal slings and synthetic midurethral slings, and written two textbook chapters on female pelvic surgery. He is currently the Principal Investigator developing a rabbit model for the evaluation of polypropylene and absorbable meshes. Dr. Winkler has also been a reviewer for the International Urogynecology Journal, Female Pelvic Medicine and Reconstructive Surgery, and the American Journal of Obstetrics and Gynecology, as well as was an abstract reviewer for the AUGS 2015 Annual Meeting.

Dr. Winkler has broad clinical experience. During the course of his career, Dr. Winkler has performed several thousand procedures treating female stress urinary incontinence ("SUI") and pelvic organ prolapse ("POP"). Prolift Report at 4-7 (Ex. A); TVT Report at 4-8 (Ex. B). Having practiced both before and after the development of pelvic mesh devices, he has extensive

experience performing an array of pelvic reconstructive procedures using patients' native tissue, cadaveric tissue, animal tissue and synthetic materials. He is experienced in performing open abdominal, laparoscopic and transvaginal procedures, and identifying which patients are appropriate candidates for these procedures. He also understands the risks and benefits associated with each procedure.

BASES OF DR. WINKLER'S OPINIONS

In addition to his extensive surgical experience performing pelvic floor surgery, Dr. Winkler bases his opinions on his exhaustive review of the medical literature, including Level 1 evidence. In particular, Dr. Winkler's opinions are supported by findings reported in:

- Meta-analyses, considered to be one of the highest levels of clinical evidence, analyzing surgeries for vaginal prolapse including:
    - The most recent (2016) Cochrane reviews by Maher, et al. on surgery for women with apical vaginal prolapse and comparing transvaginal mesh or grafts with native tissue repair for vaginal prolapse, and Cundiff, et al. on the risk factors of mesh or suture erosion following sacrocolpopexy;
    - A 2014 meta-analysis of the impact of native tissue repair for POP on sexual function by Jha and Gray; and
    - A 2010 meta-analysis on the outcomes of transvaginal uterosacral ligament suspension by Margulies, et al.
- Meta-analyses of surgeries for stress urinary incontinence including;
    - A 1997 AUA Guidelines meta-analysis published by Leach, et al. on the surgical management of SUI;

- A 2011 meta-analysis of the effectiveness of midurethral slings in mixed urinary incontinence by Jain, et al.;
- A 2012 meta-analysis of the effectiveness of midurethral slings in recurrent SUI by Pradhan, et al.;
- A 2016 meta-analysis of the influence of body mass index on the outcome of midurethral sling procedures for SUI by Xia, et al.;
- A 2008 meta-analysis by Novara, et al. comparing the complication rates of tension-free midurethral slings to other surgical procedures and devices for SUI, and the 2010 update of that analysis;
- A 2014 meta-analysis by Schimph, et al. on sling surgery for SUI; and
- Cochrane reviews of mechanical midurethral slings by Rehman,et al. in 2011; Lipp, et al. in 2014, Glazener in 2014, and Ford, et al. in 2015.

- Long-term data from randomized controlled trials (Level 1 evidence) studying the outcomes of the surgical treatment for POP using pelvic mesh and native tissue by Maher, et al. (2004), Roovers, et al. (2004), Hiltunen, et al. (2007), Nguyen, et al. (2008), Carey, et al. (2009), Nieminen, et al. (2010), Altman, et al. (2011), Culligan, et al. (2011), Maher, et al. (2011), Paraiso, et al. (2011), Withagen, et al. (2011), Sokol, et al. (2012), Barber, et al, (2014), Rondini, et al. (2015), and Kenton, et al. (2016).
- Long-term data from randomized controlled trials (Level 1 evidence) studying the outcomes of the surgical and nonsurgical treatment for SUI including the use of mesh slings and native tissue by Ward, et al. (2000), Liapis, et al. (2002), Paraiso,

et al. (2004), Albo, et al. (2007), Ward, et al. (2007), Richter, et al. (2012), and Wai, et al. (2013)

In his two reports, Dr. Winkler cites to over 200 publications in the medical literature and relies upon far more publications, expert reports and professional society statements in reaching his opinion. *See* Prolift Report at 42-48 (ex. A); TVT Report at 42-46 (Ex. B); Reliance List, (Ex. C). Importantly, he provides a detailed analysis of these publications' findings and a practical synthesis of the evolution of treatment for both SUI and POP based on the medical evidence they provide.

LEGAL STANDARD

Ethicon incorporates by reference the standard of review for *Daubert* as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 WL 3361923 at *1-3 (S.D. W. Va. July 8, 2014).

LEGAL ARGUMENT

I. Dr. Winkler is qualified to testify as to the risks of implanting mesh and whether those risks were contained in Ethicon's warnings or were otherwise commonly known to pelvic floor surgeons.

As discussed above, Dr. Winkler is a highly-trained Board Certified urogynecologist and surgeon with a subspecialty in Female Pelvic Medicine and Reconstructive Surgery. *See e.g.*, Prolift Report at 1-2 (Ex. A). Ethicon concedes that Dr. Winkler is not a regulatory expert and will not opine on warnings from that perspective. Consistent with the Court's prior rulings, however, Dr. Winkler, as a urogynecologist, "may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4582231, at *3 (S.D.W. Va. Sept. 1, 2016). Indeed, Dr. Winkler's reports and deposition testimony detail his extensive experience with these devices,

including particular risks and complications he has experienced and researched, and his reports explain his opinions in detail.

Importantly, Plaintiffs do not challenge Dr. Winkler's competency to testify that risks which did not appear in the IFUs were already commonly known to clinicians. *Compare In re: Ethicon*, 2016 WL 4582231, at *3 n. 2 (finding that Plaintiffs had not challenged this issue). To the extent that their motion is construed as doing so, any such challenge should be denied. Dr. Winkler will testify that the complications Plaintiffs' experts claim should have been in the IFUs: (a) are risks that pelvic surgeons commonly know, and therefore, do not need to be warned about; (b) are not genuine complications; or (c) are not attributable to the device. *E.g.*, Prolift Report at 15-22 (Ex. A); TVT Report at 37-42 (Ex. B). As they relate to the latter two categories, Dr. Winkler's opinions are based on extensive clinical experience, as well as a thorough critique of the scientific literature. *See Huskey* v. Ethicon, Inc., 29 F. Supp. 3d 691, 734-35 (S.D.W. Va. 2014) (allowing Dr. Johnson to testify about evidence of absence because his opinions were also based on medical literature); *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *12 (S.D. W.Va. Apr. 28, 2015).

Contrary to Plaintiffs' suggestion, expertise in federal regulations is not required to reach these opinions. (Pls. Mem. at 4-5.) "[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *15 (S.D.W. Va. Apr. 24, 2015) (quoting *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, No. 3:09–md–02100, 2011 WL 6301625, at *11 (S.D.Ill.Dec.16, 2011)). A physician is qualified to make a comparison between "the risks he

perceives that the [device] poses to patients" and whether the labels "convey these risks to physicians." *Id.* (finding physician qualified to give opinions on product labeling based on his clinical experience because his testimony did not touch on regulatory issues). Moreover, a physician is qualified to testify about the completeness of IFUs from a clinical perspective, despite lack of familiarity with FDA regulations and requirements for warnings, or prior experience drafting IFUs. *Id.* at *6-7, 15 (finding physician qualified to provide opinion on IFUs based on clinical experience despite lack of familiarity with FDA rules or regulations for warnings).

As an experienced clinician and educator, Dr. Winkler is also well-qualified to testify about complications that are "commonly known" such that they need not be included in an IFU. The law imposes no duty to warn sophisticated users of products with respect to risks that the sophisticated users already know or should know. *See, e.g.*, Restatement (Third) of Torts: Product Liability § 2 cmt. j (1998); Restatement (Second) of the Law of Torts § 402A cmt. j; American Law of Product Liability 3d § 32:69 (2016); *Willis v. Raymark Indus., Inc.*, 905 F.2d 793, 797 (4th Cir. 1990); *Roney v. Gencorp*, 654 F. Supp. 2d 501 (S.D. W. Va. 2009) (adopting "sophisticated user" defense in §388). The test is an objective one that depends on the knowledge of foreseeable users generally, not on the knowledge of the person whose use is at issue in the particular case. *Johnson v. American Standard, Inc*., 179 P.3d 905, 914 (Cal. 2008) (sophisticated user "knew or should have known" of the danger).

Accordingly, there is no duty to warn of risks commonly known to implanting surgeons. *See Brooks v. Medtronic, Inc*., 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers

"not well known to the medical community."). In fact, the FDA device regulations say that information may be omitted from labeling:

> if, but only if, the article is a device for which directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device.

21 C.F.R. §801.10(c) (emphasis added). *See also Wright ex rel. Trust Co. of Kansas v. Abbot Laboratories, Inc.*, 259 F.3d 1226, 1234 (10th Cir. 2001) (drug company had no duty to warn hospital of the danger of stocking different concentrations of saline solution in the same place); *Brown v. Drake-Willock Intern. Ltd.*, 530 N.W. 2d 510, 516 (Mich. App. 1995) (physician was sophisticated user of dialysis machine).

The IFUs at issue here restrict the class of surgeons who are to use the devices. The Gynemesh PS IFU says, "Users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing GYNECARE GYNEMESH PS for pelvic reconstruction."(ETH.MESH.02342252 (English language excerpt attached as Ex. D)). The Prolift IFU says, "Users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing the GYNECARE PROLIFT Pelvic Floor Repair Systems." (ETH.MESH.2341527 (English language excerpt attached as Ex. E)). The TVT IFU says, "The device should be used only by physicians trained in the surgical treatment of Stress Urinary Incontinence." (ETH.MESH.05225380 (English language excerpt attached as Ex. F)). The TVT Exact IFU says, "The device should be used only by physicians trained in the surgical treatment of Stress Urinary Incontinence and specifically in the use of the GYNECARE TVT EXACT* Continence System." (ETH.MESH.05799237 (English language excerpt attached as Ex. G)). As such, Plaintiffs'

failure to warn claims depends on what "hazards" were "commonly" known to surgeons familiar with pelvic floor repair as well as non-absorbable meshes.

Furthermore, Dr. Winkler's opinions regarding the knowledge common to pelvic floor surgeons is not "state-of-mind" testimony. (Pls. Mem. at 7-8.) Dr. Winkler does not pretend to know what any particular doctor, much less what all doctors know. *Id.* at 7. Rather, his opinion addresses the knowledge "commonly known" to pelvic floor surgeons based on his review of the medical literature, as well as his extensive education and training, communications with other pelvic floor surgeons and his experience as a professor in the field. TVT Report at 41 (Ex. B). Such objective testimony from a qualified expert like Dr. Winkler is appropriate and necessary to determine which risks a manufacturer is required to disclose. Without it, a jury would be unable to reach the necessary legal conclusion on the completeness of warnings.

Moreover, Dr. Winkler's statement regarding patient knowledge, which Plaintiffs inaccurately paraphrase, is similarly general: "Patients themselves intuitively are aware that *there are risks* to surgery." TVT Report at 40 (emphasis added) (Ex. B). It does not speak to the particular knowledge held in the mind of any particular person, but is a simple acknowledgement that it is common for patients to know that surgery is not risk-free.

Accordingly, Dr. Winkler should not be precluding from testifying about the completeness of Ethicon's warnings because his opinions are based on his considerable experience, training, education, communications with other pelvic floor surgeons, extensive review of medical literature, and his sound understanding of the risks commonly known to pelvic floor surgeons.

II. Dr. Winkler's opinions pertaining to Ethicon's conduct are relevant because they address the safety and efficacy of Ethicon's devices and are based on sound methodology he employed in the purview of his expertise as a pelvic floor surgeon.

Dr. Winkler does not opine upon industry practices or corporate compliance, as Plaintiffs suggest, but rather upon the safety and efficacy of Ethicon's pelvic mesh devices – opinions he is qualified to render. The one example Plaintiffs offer to support their argument is Dr. Winkler's statement in his TVT report that "it was appropriate for Ethicon to not introduce changes to [mechanically cut TVT] mesh too rapidly." TVT Report at 28 (Ex. B). That statement is based on "the large volume of date that existed on the safety and efficacy of mechanically cut TVT," including the finding "described by Moalli et al (2008) [that] altering a mesh might change the characteristics" which could affect the "way mesh performs," and another theory that the rough edges of mechanically cut mesh "were the most important property of the mesh holding the sling in place in the early postoperative days." *Id.*

These opinions are not personal to Dr. Winkler nor based on a supposed expertise in corporate conduct. They are based on Dr. Winkler's clinical observations of the safety and effectiveness of Ethicon's pelvic mesh devices, as well as his extensive understanding of the medical literature analyzing the safety and efficacy of mechanically cut mesh, and the *lack* of "reliable clinical data . . . demonstrat[ing] a *decrease* in complications that are attributed to whether the mesh is mechanically cut or laser cut." *Id.* (emphasis added). Because Dr. Winkler's opinions on the appropriateness of Ethicon's conduct relate to the safety and efficacy of its SUI and POP products, and those opinions are based on his extensive review of the clinical data and experience as a clinician, they are relevant and he is qualified to render them.

III. Dr. Winkler's opinion on the safety of mechanical and laser cut mesh, and the appropriateness of Ethicon's use of these materials, is based on sound methodology.

Plaintiffs misstate Dr. Winkler's opinion regarding mechanically cut mesh (MCM) and laser cut mesh (LCM) as a broad conclusion that "there is no difference between the TVT-R mechanically cut and the TVT-R laser cut." (Pls. Mem. at 6.) In fact, Dr. Winkler states more precisely that, after personally implanting thousands of midurethral slings constructed of both MCM and LCM, he has "not noticed a difference in complications." TVT Report at 7 (Ex. B). This distinction is critical. Dr. Winkler does not opine that no difference exist between MCM and LCM. His opinion is based on the absence of any reliable data to support Plaintiffs' claim that such a difference exists. *Id.* at 42-45 (Ex. B).

It is not Dr. Winkler or the Defense's burden to prove a negative. It is Plaintiffs' burden to support their claim, with sound methodology, that complication rates between MCM and LCM differ. To require Dr. Winkler to present data that demonstrates no difference exists would shift the Plaintiffs' burden to the Defense.

Moreover, Plaintiffs make much of the fact that Dr. Winkler testified he could not recall implanting laser-cut TVT-R or cite a study that compared mechanically cut TVT-R with laser cut TVT-R. (Pls. Mem. at 6.) However, Plaintiffs' ignore Dr. Winkler's experience implanting TVT Exact, which is made only with laser cut mesh, as well as his reliance on the work of Thurber et al. (2016), comparing complication rates of TVT and TVT Exact, and Lim et al (2010), comparing TVT and Advantage (another laser cut sling), neither of which found demonstrable differences in complications or effective cure rates. TVT Report at 42 (Ex. B). This data and Dr. Winkler's clinical experience soundly support his opinion that no difference in the safety or effectiveness of MCM and LCM has been demonstrated. Whether such a difference

can be shown when comparing mechanically cut TVT to laser cut TVT specifically is Plaintiffs' burden. But there is no basis to exclude Dr. Winkler's opinion that no sound evidence demonstrates a difference in the comparative safety and efficacy of MCM and LCM.

IV. Dr. Winkler's testimony about the comparative safety of mesh and non-mesh procedures is reliable.

First, Plaintiffs' critique of Dr. Winkler's opinion as "guess-work" because he did not provide a statistical analysis of his findings does not render his opinion unreliable. (Pls. Mem. at 10-12.) A physician's "knowledge, experience, and review of scientific literature provide sufficiently reliable bases for his opinions under *Daubert*." *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 714 (S.D.W. Va. 2014). This Court in particular has made clear that a physician can draw upon his clinical experience and review of relevant literature – as Dr. Winkler has done – to offer opinions on a product's safety and efficacy. *See Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014) (finding that a urologist with extensive clinical experience and relying upon peer-reviewed literature could opine on the safety and efficacy of mesh products).

Nor did Dr. Winkler "assume" his personal experience matched the complication rates in the medical literature. (Pls. Mem. at 12.) His reliance on his thorough review of peer-reviewed publications and corroborated by his personal experience provides a sound methodology for formulating his opinions regarding the safety and utility of the devices at issue. Prolift Report at 19-22 (Ex. A); TVT Report at 29-37 (Ex. B). This Court has recognized that a physician may testify that complication rates found in the medical literature are verified by his personal experience. *See, e.g., Tyree v. Boston Scientific Corp*, 54 F. Supp. 3d 501, 585 (S.D. W. Va. 2014) (expert's opinion about safety and efficacy was reliable where opinion was based upon

"minimal complications in his clinical practice" which was "'on par with the findings of [the] studies' he cites throughout his expert report"); *Carlson*, 2015 WL 1931311, at *12, *36 (finding Dr. Galloway's method of considering scientific articles and drawing on his clinical experience to reach his opinion regarding degradation to be methodologically sound and allowing Dr. Culligan "by way of his experience with the Uphold device and his review of the relevant scientific literature" to opine upon how these procedures compare).

This Court rejected a similar argument in *Bellew v. Ethicon, Inc.*:

> The plaintiff takes issue with Dr. Robboy's reliance on his clinical experience because she has no way of "independently verifying" opinions. The plaintiff's argument has no practical merit. Numerous expert witnesses throughout the course of these MDLs have relied on their clinical experience in forming their expert opinions. Such practice can hardly be described as a "mystery." If *Daubert* required an expert witness to independently verify every single clinical experience he had over the course of his career, the court would never make it past pre-trial motions.

No. 2:13-cv-22473, Doc. 265, p. 40 (S.D. W. Va. Nov. 20, 2014); *see also Winebarger*, 2015 WL 1887222, at *34 (finding that expert's inability to provide "exact statistics" about the outcome of his patients did not render his personal experience opinions unreliable and that "such detail is not required under *Daubert* to opine as to '*large-scale* safety and efficacy of the Uphold device'"); *Trevino*, 2016 WL 2939521, at *33 (same).

For these same reasons, the Court should reject Plaintiffs' argument here. Physicians routinely counsel patients considering surgery on the physicians' experienced-based perception of their own patients' complication rates. Simply because Dr. Winkler did not reduce his patients' complication rates to a statistical analysis does not render his experience unhelpful or unscientific.

Second, Plaintiffs' again mischaracterize Dr. Winkler's testimony. He never testified or stated in either of his reports that mesh products are "as safe" as alternative treatments. (Pls. Mem. at 8.) Indeed, Dr. Winkler's testimony belies this characterization:

> Q. You're establishing that Prolift and Gynemesh PS are safe because you think they're safe as native tissue repair; is that fair?
>
> A. Based on the literature I reviewed, there's no increase in rate of dyspareunia rates and chronic pain rates.
>
> Q. Right. So saying there's no increase in one rate as compared to the other one, I have no idea what rates you're comparing. It's not – I'm not trying to belabor this, but –
>
> A. I wish studies would give a rate exactly. That would make all of our lives easier, but it's a variable rate and takes into account multiple factors, and that's why we don't have that specific rate that you're asking for.

Deposition of Dr. Harvey Winkler re: Gynemesh PS and Prolift (Wave 4) ("Prolift Dep.") at 107:12-108:5 (Ex. H). In other words, Dr. Winkler's exhaustive review of the medical literature discussed above, verified by his own extensive clinical experience, underpins his opinion that different studies involving pelvic mesh and alternative procedures produced different ranges of complication rates based on variables in those studies, but that those ranges do not demonstrate increased complication rates for procedures using pelvic mesh. TVT Report at 29-37 (Ex. B). *See also* Deposition of Dr. Harvey Winkler re: TVT and TVT Exact (Wave 4) ("TVT Dep.") at 292:24-294:10 (Ex. I).

Plaintiffs' claim that Dr. Winkler's opinion relies on selective results of a 2016 Cochrane review also fails to accurately characterize his more nuanced testimony. (Pls. Mem. at 10-12.) Dr. Winkler did not ignore findings of the Cochrane review regarding the use of mesh in primary surgical patients. He relied on results of the review together with the results of other studies and

ACOG guidelines, which were consistent with results seen in his clinical practice. Prolift Dep. at 62:21-24; 72:16-22 (Ex. H). Nor did he agree, as Plaintiffs suggest, that "mesh should not be used in primary surgery." (Pls. Mem. at 11.) Rather, he testified that there are certain patient populations for whom, depending on their "goals and expectations from the surgical procedure," "transvaginal mesh may be more or less appropriate." Prolift Dep. at 71: 17-20-72:3 (Ex. H).

Plaintiffs' criticisms of the reliability of Dr. Winkler's opinions are inaccurate and fail to mount a successful *Daubert* challenge. As such, they should be disregarded by the Court.

V. Dr. Winkler's opinion regarding alleged mesh degradation in vivo is reliable.

Here again, Plaintiffs mischaracterize Dr. Winkler's opinion and testimony. (Pls. Mem. at 12.) Relying on both medical literature and his personal experience, Dr. Winkler concludes that "TVT mesh does not degrade in vivo. Studies suggesting that degradation occurs have not demonstrated any link to complications and alleged degradation, and any suggestion that alleged degradation causes complications is not based on any reliable scientific data." TVT Report at 48. Questioned at his deposition about evidence of mesh fibers falling off of a TVT sling before it was implanted and whether he was aware of any studies demonstrating that particles did not fall off once implanted, Dr. Winkler responded that there are no studies that would "show complete breakage of mesh fibers in vivo." TVT Dep at 176:7-178:12 (Ex. I).

This is yet another instance of Plaintiffs attempting to burden the Defense with proving a negative. It is Plaintiffs' burden to prove their claim, through reliable methodology, that mesh degrades or loses particles in vivo with a clinically significant link to a complication. Regardless of whether Plaintiff can produce reliable evidence to support their claim, Dr. Winkler's opinion that no reliable evidence exists to support the claim is reliable, and therefore admissible, because

it is based on the medical literature and verified through his personal experience. Accordingly, this opinion, along with the other opinions expressed in his reports and his testimony should be admitted.

CONCLUSION

For these reasons, Plaintiffs' Motion to Exclude Certain Opinions and Testimony of Ethicon's Expert Dr. Winkler should be DENIED.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 27, 2017, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Kelly S. Crawford
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